

## REMARKS/ARGUMENTS

### Election

Applicants herein elect, with traverse, Group I (claims 1 and 2) and SEQ ID NO:1 for prosecution on the merits.

Applicants respectfully disagree with, and traverse the Sequence Election Requirement.

Applicants intend that SEQ ID NOS:1-3 be presented and interpreted as a Markush-type grouping of amino acid sequences which share a common utility (all are related to insulin resistance). Markush-type claims are defined as a grouping including a plurality of alternatively usable substances or members (MPEP 803.02). At page 46, lines 6-14 SEQ ID NOS:1-3 are disclosed as a group of disease specific markers related to insulin resistance. Thus, the entire group (SEQ ID NOS:1-3), selected members or any one of SEQ ID NOS:1-3 can be alternatively used as a disease specific marker(s) related to insulin resistance.

The Examiner asserts that each sequence is patentably distinct because they are unrelated sequences. Applicants respectfully disagree with the Examiner's assertion and emphasize the fact that SEQ ID NOS:1-3 are all fragments of the same parent protein, complement C3 precursor protein (see page 46, lines 6-14 of the instant specification).

It has been established that it is improper for the Office to refuse to examine that which applicant regards as their invention,

unless the subject matter in a claim lacks unity of invention. Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. See MPEP 803.02; *In re Weber* 198 USPQ 328 (CCPA 1978); *In re Haas* 198 USPQ 334 (CCPA 1978); *In re Harnish* 206 USPQ 300 (CCPA 1980); *Ex parte Hozumi* 3 USPQ2d 1059 (Board of Patent Appeals and Interferences 1984).

SEQ ID NOS:1-3 are all biopolymer markers related to the condition of insulin resistance and thus share a common utility in the diagnosis and/or treatment of insulin resistance. SEQ ID NOS:1-3 are all fragments of complement C3 precursor protein and thus also share a common structural feature.

Accordingly, Applicants respectfully assert that claims reciting the Markush group of SEQ ID NOS:1-3 have unity of invention and respectfully request that the Office examine all sequences together.

Additionally, in contrast to Applicants presentation of SEQ ID NOS:1-3 in a Markush-type grouping, the Sequence Election Requirement presents each of SEQ ID NOS:1-3 as unrelated, patentably distinct sequences, thus introducing a contradiction into the prosecution history. Since Applicants are required to elect a Group (and a single sequence) for prosecution on the merits, one reading the prosecution history may incorrectly assume

that Applicants admit SEQ ID NOS:1-3 are separate and distinct inventions. Such contradictions can potentially diminish the value of any patent that may issue from the instant application.

Now that it has been shown that SEQ ID NOS:1-3 have unity of invention, Applicants respectfully request that the Examiner reconsider the Sequence Election Requirement.

#### **Claim Status/Support for Amendments**

Claim 1 has been amended. Claims 2-38 have been cancelled. New claims 39-46 have been added. Claims 1 and 39-46 remain pending in the instant application.

No new matter has been added by the amendments to claim 1. Claim 1 has been amended to recite only elected SEQ ID NO:1 and to incorporate the subject matter of cancelled claim 2. Claim 1 has also been amended to clarify that the claimed peptide (SEQ ID NO:1) has been isolated from its naturally occurring state; see page 20, lines 9-16 of the instant specification for support.

No new matter has been added by the addition of new claims 39-46. The subject matter of new claims 39-46 corresponds with subject matter originally found in cancelled claims 2-38. The above additions to the claims also find basis in the original disclosure at page 25, line 16 to page 26, line 22. The method of new claim 39 is described in detail at pages 37-47. Page 47, line 23 to page 48, line 4 refer to use of various types of samples and page 38,

line 22 to page 39, line 12 refer to different mass spectrometric techniques. Page 46, line 23 refers to practicing the claimed methods with a human patient. Pages 47-48 describe kits contemplated for use with the claimed methods. Page 47, lines 18-23 refer particularly to the immobilizing on solid supports and labeling of components of the contemplated kits. It is clear from these specific recitations and from the description of methods utilized that the methods and types of kits recited in the newly added claims (39-46) were fully contemplated by the inventors at the time of filing and were enabled by virtue of the disclosure as originally filed.

CONCLUSION

Now that Applicants have fully responded to the Office Action mailed on October 7, 2004, an examination on the merits is respectfully requested.

Respectfully submitted,

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